



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2011-0095]

Monsanto Co.; Determination of Nonregulated Status of Soybean Genetically Engineered to Produce Stearidonic Acid

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that a soybean line developed by the Monsanto Co., designated as event MON 87769, which has been genetically engineered to produce stearidonic acid, an omega-3 fatty acid not found in conventional soybean, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by the Monsanto Company in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notice announcing the availability of the petition for nonregulated status and its associated environmental assessment and plant pest risk assessment. This notice also announces the availability of our written determination and finding of no significant impact.

EFFECTIVE DATE: [Insert date of publication in the Federal Register].

ADDRESSES: You may read the documents referenced in this notice and the comments we received in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is

there to help you, please call (202) 799-7039 before coming. Those documents are also available on the Internet at http://www.aphis.usda.gov/biotechnology/not_reg.html and are posted with the previous notice and the comments we received on the Regulations.gov Web site at <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0095>.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the documents referenced in this notice, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS received a petition (APHIS Petition Number 09-183-01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status of soybean (Glycine max) designated as event MON 87769, which has been genetically engineered to produce stearidonic acid, an omega-3 fatty acid not found in conventional soybean. The petition stated that this soybean is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

In a notice¹ published in the Federal Register on December 27, 2011 (76 FR 80871-80872, Docket No. APHIS-2011-0095), APHIS announced the availability of the Monsanto petition, a plant pest risk assessment (PPRA), and a draft environmental assessment (EA) for public comment. APHIS solicited comments on the petition, whether the subject soybean are likely to pose a plant pest risk, the draft EA, and the PPRA for 60 days ending on February 27, 2012.

APHIS received 226 comments during the comment period, with 21 commenters expressing support of a determination of nonregulated status and the remaining 205 commenters expressing opposition. Issues raised during the comment period include socioeconomic impacts, changes in nutrition caused by the product, environmental impacts, changes in soybean properties, and product safety. APHIS has addressed the issues raised during the comment period and has provided responses to these comments as an attachment to the finding of no significant impact.

¹ To view the notice, petition, draft EA, the PPRA, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0095>.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with a determination of nonregulated status of Monsanto's soybean event MON 87769, an EA has been prepared. The EA was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a finding of no significant impact with regard to the preferred alternative identified in the EA.

Determination

Based on APHIS' analysis of field and laboratory data submitted by Monsanto, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that Monsanto's soybean event MON 87769 is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the introduction of certain genetically engineered organisms.

Copies of the signed determination document, as well as copies of the petition, PPRA, EA, finding of no significant impact, and response to comments are available as indicated in the ADDRESSES and FOR FURTHER INFORMATION CONTACT sections of this notice.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 9th day of July 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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